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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/016,850

12/14/2001

Patrick M. Hughes

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51957 7590 08/04/2009  
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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

08/04/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/016,850	<b>Applicant(s)</b> HUGHES ET AL.	
	<b>Examiner</b> ZOHREH A. FAY	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-16 and 24-26 is/are pending in the application.  
4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-12, 14-16 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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Claims 1-12, 14-16 and 24-26 are pending in the instant application.

Claim 10 has been withdrawn from consideration.

Claims 13 and 17-23 are withdrawn from consideration.

Claims 1, 7, 9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/92288 for the reasons set forth on page 2 of the office action of December 2, 2008.

Claims 1-6, 7, 8, 9, 11-12, 14-16 and 24-26 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Desantis, JR. (US 2001/0047012) and Collins et al. (WO 01/92288) for the reasons set forth on pages 2-4 of the office action of December 8, 2008.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant alleges criticality to the differences in function of the claimed combination and the combination of the prior art. Appellant is reminded that the claims of the instant application are composition claims, therefore the intended use confer no patentable weight to the composition claims. Applicant's declaration has been carefully considered, but is not deemed to be persuasive. Applicant appears to have discovered another advantage of an old composition, which is being delivered to the posterior segment of the eye in an amount of several folds that delivered to the anterior segment of the eye. Applicant's attention is drawn to In re Best and In re Fitzgerald. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (250 USPO 594) discuss support of rejection wherein the prior art discloses subject matter, which there is reason to believe inherently includes function that are newly cited or is identical

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to product instantly claimed. In such situation the burden is shifted to the applicant to “prove that subject matter to be shown in the prior art does not possess the characteristic relied on “ (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter in fact is inherent in the prior art reference. *Schering Corp v. Geneva Pharm. Inc.*, 339 F. 3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004). In the instant case applicant is using the same composition as prior art by applying it to the eye, therefore it is expected that such composition would inherently act the same as the composition of the instant application.

In conclusion, *Desantis* teaches a combination of brimonidine and memantine (elected species by appellant) in an ophthalmic formulation for the treatment of glaucoma. *Collins et al.* teach pharmaceutical conjugates with ophthalmic application. Efficacy enhancing components of Formula A are disclosed on page 92. The applied references teach the combination of compounds of formula A, such as memantine in combination with therapeutic agents such as brimonidine. The specification fails to define a “conjugate” as anything more than the combination of compounds wherein the increased solubility or bioavailability is sought.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF  
/Zohreh A Fay/  
Primary Examiner, Art Unit 1612